## REMARKS

This is a full and timely response to the Office Action dated January 25, 2008. Applicant respectfully requests reconsideration of the present application in view of the following remarks.

Claims 1-13 are currently pending, with claims 1, 4, 6, 10, 11 and 13 being independent.

Claims 1 - 13 are currently amended. No new matter has been added.

**Claim Rejection under 35 U.S.C. §103(a)**

**Claims 1-3 are rejected under 35 USC §103 (a) as being unpatentable over *Turcott*. (U.S. Patent No. 6,409,675) in view of Montserrat et al ("Effectiveness of CPAP Treatment in Daytime Function in Sleep Apnea Syndrome").** The rejection is respectfully traversed for at least the reasons set forth below.

When evaluating a claim for determining obviousness, all limitations of the claim must be considered. Under 35 U. S. C. 103, it provides that:

> a patent may not be obtained if the differences between the subject matter sought to be patented and the prior art are such that *the subject matter as a whole* would have been obvious at the time the invention was made to a person having ordinary skill in the art to which the subject matter pertains. (Emphasis added.)

Further, in establishing a *prima facie* case of obviousness under 35 U.S.C. § 103, the prior art reference (or references when combined) must teach or suggest each and every claim limitation. *See, e.g., In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974); *accord*. MPEP 2143.03.

*Turcott* mainly discloses an **implantable** monitor, in contrast the monitor in the current invention is **attached on the body of a patient**. However, as the Office Action states, Applicant acknowledges that *Turcott* states that "in another embodiment the monitor is **not implanted** but rather is attached or worn externally by the patient daily for extended periods, such as during sleep."

(Column 7, lines 25-27) However, the non-implanted monitor in *Turcott* has ONLY **the vascular plethysmography and arterial $O_2$ saturation sensors** as recited below (Column 11, lines 41-44).

> *As with most of the sensors described here, the vascular plethysmography and arterial $O_2$ saturation sensors can be used in noninvasive, external embodiments, in contrast to incorporation in an implantantable monitor.*

In contrast, the monitor in the current invention has "a unit for measuring and recording an airflow information about presence / absence or magnitude of respiratory airflow of the subject patient, and a unit for measuring and recording an electrocardiogram wave form of the subject patient having an electrode part..." as recited in claim 1. Accordingly, *Turcott* does not teach or suggest such units cited in claim 1.

Further, such sensors disclosed by *Turcott* can be made small and can conveniently attach to a **peripheral portion of the body**, such as finger, toe, or ear... Particular embodiments include a finger cuff, a wristband, a configuration resembling a watch, and a configuration resembling a clip-on earring. (Column 11, lines 49-57). In contrast, the monitoring system in the current invention is **attached on the body of the subject patient**.

More importantly, *Turcott* does not disclose "An examination apparatus for use in selecting a patient for whom an oxygen therapy is effective among patients having a sleep respiratory disturbance". The Office Action acknowledged that *Turcott* does not disclose this regard.

Further, *Turcott* discloses the heart rate transition in Fig. 14 and analyzing higher level information such as the RR interval. (Column 15, lines 21-34). However, *Turcott* does not teach or suggest a claimed feature "an analysis unit for analyzing the enhanced state of sympathetic nerves based on the measured electrocardiogram wave form." Additionally, *Turcott* does not disclose "an output part for displaying or printing both of: (A) a transition of respiratory airflow; and (B) a transition of enhanced state of sympathetic nerves, of the subject patient during sleeping," (emphasis added) as recited in claim 1. As shown below in Step 3 of the Specification, it is an important claim feature for this invention to have an output part for displaying or printing BOTH of (A) and (B), cited above, in order to obtain the effective result.

*[Decision for Necessity to Carry out an Oxygen Therapy (Step S3)]*

*[0126] The report transmitted to the medical institution includes graphs showing each determination as illustrated in schematic view in FIG. 4. In FIG. 4, T1 and T3 represent a zone showing normal respiration; T2 represents a zone showing a Cheyne-Stokes respiratory symptom as a typical example of a sleep respiratory disturbance; "a" denotes a graph showing transition of a respiratory airflow level; "b" denotes a graph showing transition of enhancement of sympathetic nerve of the subject patient detected by the process of heart rate variability analysis.*

*[0127] Based on these contents in the report and other information, the medical service worker in the medical institution studies as to whether or not a sleep respiratory disturbance and enhancement of sympathetic nerve are found in this subject patient, and decision is made on whether or not an oxygen therapy should be carried out on the subject patient based on this study result.*

*[0128] The decision is made, for example, as follows. In illustrations in FIG. 4, referring to the respiratory airflow level "a" of this patient first, it can be found that constant level was kept in the period of T1 (a1), however, in the period of T2, abnormal respiration state was exhibited in which wave forms a2 and a4 showing apnea with lowered level, and wave forms a3 and a5 with repeating temporal increase and temporal decrease in the level are repeated. In addition, wave forms showing abnormal respiration other than Cheyne-Stokes respiratory symptoms illustrated in FIG. 4 may possibly exist.*

*[0129] Further, referring to the graph "b" showing transition of enhancement of sympathetic nerve, in the region b1 corresponding to the region a1 with normal respiratory airflow level, enhanced state of sympathetic nerve is found to be below the previously defined threshold b0. It is also found that in the regions b2 and b4 corresponding to the regions a2 and a4 showing apnea for the respiratory airflow level, enhancement of sympathetic nerve was temporarily increased to exceed the threshold b0, and in the regions a3 and a5 with repeating temporal increase and temporal decrease in the respiratory airflow level, the enhancement of sympathetic nerve reached to its peak, and turned into temporal decrease. Moreover, when the respiratory airflow level departs from the abnormal respiration zone T2 to enter the normal respiration zone T3, enhancement of sympathetic nerve is also decreased to be below the threshold b0.*

*[0130] From the observation results as described above, the medical service worker recognizes that: (1) a sleep respiratory disturbance is found in the subject patient; (2) enhancement of sympathetic nerve is found concurrent with development of this sleep respiratory disturbance; and (3) transition of state of enhancement of sympathetic nerve occurs in conjunction with transition of respiration airflow during development*

*of a sleep respiratory disturbance.*

*[0131] From these findings, the medical service worker can definitely and obviously learn manifestation of enhancement of sympathetic nerve resulting from the sleep respiratory disturbance. Accordingly, effectiveness of an oxygen therapy for this sleep respiratory disturbance and enhancement of sympathetic nerve can be definitely and obviously learned, therefore, an instruction to carry out an oxygen therapy on this patient can be certainly conducted.*

Lastly, claim 1 is directed to "an electrode part which can be stuck on the skin of the subject patient." *Turcott*, in fact, discloses electrodes (such as reference numeral 22 in Figs. 2 and 3) for electrocardiogram (ECG). However, Figs. 2 and 3 are for **implantable/implantantable** monitors. Any non-implantable monitors in *Turcott* do NOT disclose, teach or suggest such electrodes since such a non-implantable monitor does not carry electrocardiogram.

Further, *Montserrat* discloses Continuous Positive Airway Pressure (CPAP) is effective for sleep apnea/hypopnea syndrome. According to dictionary.com, CPAP is defined as "*A technique of respiratory therapy for individuals breathing with or without mechanical assistance in which airway pressure is maintained above atmospheric pressure throughout the respiratory cycle by pressurization of the ventilatory circuit* (visited www.dictionary.com on April 21, 2008)." In contrast, an oxygen therapy is defined on page 2 of the Specification as a therapeutic method that "is carried out in which a supplying apparatus of a gas for respiration is installed at the patient's home; an oxygen-enriched gas supplied by this supplying apparatus of a gas for respiration is introduced to the vicinity of nasal cavity of the patient using a tubing member referred to as cannula; and the patient inhales the gas. This type of oxygen therapy is also referred to as "home oxygen therapy" (HOT). According to these definitions above, CPAP is completely different from oxygen therapy. Therefore, *Montserrat* does not teach or suggest the use of oxygen therapy and its effectiveness of the purpose of treating patients with SAHS.

To establish a *prima facie* case of obviousness, the prior art reference (or references when combined) must teach or suggest all the claim limitations. Here, *Turcott* and *Montserrat* fail to teach or suggest all the limitation of claim 1 as explained above.

Given that neither *Turcortt* nor *Montserrat* teach or suggest the claimed feature, there is no basis to assert that even a combination of these references would suggest the claimed feature. Since even a combination of the relied upon references would fail to yield the claimed invention, Applicant submits that a *prima facie* case of obviousness for claim 1 has not been presented.

Claims 2 and 3 are dependent from claim 1. It is respectfully submitted that they are allowable for at least the same reasons that claim 1 is allowable respectively stated above, and they are further allowable by reason of the additional limitations set forth therein.

**Claims 4-13 are rejected under 35 U.S.C. §103(a) as being unpatentable over Turcott (U.S. Pat. No. 6,409,675) and Montserrat et al. ("Effectiveness of CPAP Treatment in Daytime Function in Sleep Apnea Syndrome") and further in view of Thomas et al. (U.S. Pub. No. 2004/0144383).** The rejection is respectfully traversed for at least the reasons set forth below.

Claims 4, 6, 10, 11 and 13 are amended to include the same feature amended to claim 1. Further, claims 5, 7-9, and 12 depend from claims 4, 6, 10, 11 and 13. Therefore, it is respectfully submitted that they are allowable for at least the same reasons that claim 1 is allowable as stated above, and they are further allowable by reason of the additional limitations set forth therein.

## CONCLUSION

In view of the above amendment, Applicant believes the pending application is in condition for allowance.

Applicant believes no fee is due with this response. However, if a fee is due, please charge the Deposit Account No. 18-0013, under Order No. TEI-0135 from which the undersigned is authorized to draw.

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Respectfully submitted,

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